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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/796,578	02/06/97	DRIZEN A	22890-XX

EXAMINER

15M1/0116

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ART UNIT	PAPER NUMBER
1501	4

DATE MAILED: 01/16/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-44 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-44 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-44 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ *Interview* Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

–SEE OFFICE ACTION ON THE FOLLOWING PAGES–

★ U.S. GPO: 1998-404-499

Receipt is hereby acknowledged of applicants' fee, Declaration and surcharge all filed as of May 27, 1997.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-9, drawn to a stable, sterile gelled composition, classified in Class 424, subclass 484+.

II. Claims 10-28, drawn to a method for the treatment of a condition, classified in Class 424, subclass 484+.

III. Claims 29-36, drawn to an antiarthritic gelled composition, classified in Class 424, subclass 484+.

IV. Claims 37-44, drawn to a method for treating an arthritic condition, classified in Class 514, subclass 825.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as an implantation for growing new bone tissue.

Inventions Group I and Group III are related as mutually exclusive species in intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (M.P.E.P. § 806.04(b), 3rd paragraph), and the species are patentably distinct (M.P.E.P. § 806.04(h)).

In the instant case, the intermediate product is deemed to be useful as a bone cell formation/stimulating substrate and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicants traverse on the ground that the species are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Inventions Group III and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product

(M.P.E.P. § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as a method for treating an arthritic condition which comprises orally administering to an animal and/or mammal a NSAID drug dispersed within a polymer matrix.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

A telephone call was made to Gary M. Nath on July 29, 1997 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Claims 1-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. 29, 30

In claims 1, 13, 14, 15, 24, 25 and 26, the term "mean" renders the claim vague and indefinite since mean ordinarily means average which applicants have already recited in each of the noted claims. Moreover, "average molecular weight" is vague and indefinite since for high polymers such descriptive language renders the claim indefinite absent an indication on how the average molecular weight was determined such as by number average molecular weight, weight average molecular weight and the like. Correction is required.

In claims 2 and 38, the term "derivatives" renders each of the noted claims vague and indefinite. It is not clear from this disclosure whether applicants intend chemical derivatives or mechanically modified derivatives. Furthermore or in any event, derivatives would read on any molecular fragment of the parent molecule referred to and thus it is impossible to determine the subject matter covered by each of the noted claims.

In claims 6 and 7, the use of the term "polymers" lacks clear antecedent basis in claim 1 in each instance. This is because applicants use the open transitional "comprises" in claim 1 and thus allows for the presence of other polymers other than those specifically enumerated in claim 1.

In claim 8, it is not clear what the weight percents are based on. The same holds true for claim 9, claim 15, claim 1, claim 26, claim 29, claim 34, claim 35, claim 43 and claim 44.

In each of the dependent claims from claim 37 which recite a polymer, each polymer lacks clear antecedent basis in claim 37 since claim 37 sets forth plural polymers blended with plural polymers. Clarification is necessary.

Claim 21 provides for the use of a composition as a medical device, for drug delivery, the application of a diagnostic agent, or the prevention of post-operative adhesions, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 21-28 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process

claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leshchiner et al. (U.S. Patent No. 5,143,724).

Leshchiner et al. disclose biocompatible viscoelastic two-phase gel slurries wherein the first phase comprises hyaluronic acid and its salts (see column 3, lines 59-62). The second phase comprises cellulose derivatives such as carboxymethyl cellulose (CMC), hydroxypropylmethyl cellulose and hydroxyethyl cellulose (see column 4, lines 45-50). The solvent can be water. The concentration of hyaluronic acid can be from 0.15-5% by weight (see column 6, lines 61-64). The composition may contain drugs (see column 7, lines 60-65). Example 12 shows a composition comprising a 1:1 CMC-hylan gel (see column 18, lines 31-37). It would have been within the purview of one having ordinary skill

in the art at the time the invention was made to select the claimed active given the clear suggestion of a generic teaching of any drug which can be used in the gels of Leshchiner et al. and thus absent a showing of superior results in a particular drug, all drugs disclosed usable in the gels are viewed as equivalent for the purposes of Leshchiner et al.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert H. Harrison, whose telephone number is (703) 308-2422. The examiner can normally be reached on Monday-Friday from 9:30 A.M. to 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Acting Supervisor, Melvyn Marquis, can be reached on (703) 308-4320. The fax telephone number for this Group Art Unit is (703) 305-5433 or (703) 305-5408.

Any inquiry of general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-2351.

Robert H. Harrison

Robert H. Harrison
Patent Examiner
Art Unit 1501

RHHarrison:cdc
January 14, 1998